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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,225	06/27/2002	Toshio Ota	084335-0153	9216
22428	7590	10/15/2004		
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER HUNNICUTT, RACHEL KAPUST	
			ART UNIT 1647	PAPER NUMBER

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,225

Applicant(s)

OTA ET AL.

Examiner

Rachel K. Hunnicutt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 11-23 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,11-18,22 and 23 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21 is/are allowed.
- 6) ☒ Claim(s) 1,4-6,19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

RESPONSE TO AMENDMENT

Applicant's amendment filed August 17, 2004 is acknowledged. Claims 7-10 have been canceled. Claims 1, 5, 6, 19, and 20 are amended. Claims 1, 4-6, and 19-21 are under consideration. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

The objection to the specification for containing embedded hyperlinks is withdrawn in response to Applicant's amendments to the specification.

The objection to the specification regarding the use of trademarks is withdrawn in response to Applicant's amendments to the specification.

The rejections of claims 1, 5, and 19 under 35 U.S.C. 101 are withdrawn in response to Applicant's amendments to the claims. The rejection of claims 7 and 10 under 35 U.S.C. 101 is withdrawn in response to the cancellation of these claims.

The rejection of claims 1, 4-6, 19, and 20 under 35 U.S.C. 112, second paragraph regarding the term "stringent conditions" is withdrawn in response to Applicant's amendments to the claims. The rejection of claims 7-10 under 35 U.S.C. 112, second paragraph is withdrawn in response to the cancellation of these claims.

The rejection of claims 1, 4-6, 19, and 20 under 35 U.S.C. 112, second paragraph, regarding the term "functionally equivalent" is withdrawn in response to Applicant's amendments to the claims. The rejection of claims 7-10 under 35 U.S.C. 112, second paragraph is withdrawn in response to the cancellation of these claims.

The rejection of claims 1, 4-6, 19, and 20 under 35 U.S.C. 112, first paragraph, for lack of enablement, is withdrawn in response to Applicant's amendments to the claims. The rejection

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may be reinstated, however, should Applicants cancel the limitation that the sequence encoding residues 27-213 of SEQ ID NO: 2 may not be altered in response to the new matter rejection listed below. The rejection of claims 7-10 under 35 U.S.C. 112, first paragraph is withdrawn in response to the cancellation of these claims.

The rejection of claims 1, 4-6, 19, and 20 under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement, is withdrawn in response to Applicant's amendments to the claims. The rejection may be reinstated, however, should Applicants cancel the limitation that the sequence encoding residues 27-213 of SEQ ID NO: 2 may not be altered in response to the new matter rejection listed below. The rejection of claims 7-10 under 35 U.S.C. 112, first paragraph is withdrawn in response to the cancellation of these claims.

The rejection of claim 1 under 35 U.S.C. 102(a), as being anticipated by NCBI Accession No. AAD09622, is withdrawn in response to Applicant's amendment of claim 1. The rejection may be reinstated, however, should Applicants cancel the limitation that the sequence encoding residues 27-213 of SEQ ID NO: 2 may not be altered in response to the new matter rejection listed below. The rejection of claims 7-10 under 35 U.S.C. 102(a) is withdrawn in response to the cancellation of these claims.

The rejection of claims 4-6 and 19-20 under 35 U.S.C. 103(a) as being unpatentable over NCBI Accession No. AAD09622, is withdrawn in response to Applicant's amendment of claim 1. The rejection may be reinstated, however, should Applicants cancel the limitation that the sequence encoding residues 27-213 of SEQ ID NO: 2 may not be altered in response to the new matter rejection listed below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-6, and 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is drawn to a polynucleotide that "comprises an activity of a blood cell growth and differentiation factor". Polynucleotides comprise nucleotides and polypeptides comprise amino acids. Neither polynucleotides nor polypeptides "comprise" an activity. In addition, a polypeptide encoded by a polynucleotide could have such activity, but the polynucleotide itself would not have the activity. This rejection could be obviated by amending the claim to read "wherein the polynucleotide encodes a polypeptide having an activity of a blood cell growth and differentiation factor". Claims 4-6 and 19-20 are rejected as being dependent on claim 1.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-6, and 19-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1, 4-6, and 19-20 encompass polynucleotides encoding proteins comprising the "amino acid sequence according to SEQ ID NO: 2 in which one or more amino acids are replaced, deleted, inserted, and/or added at positions other than 27 to 213" (see claim 1(c)). However, nowhere in the specification is there any mention of protecting the region consisting of

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residue 27 to 213 and only replacing, deleting, inserting, and/or adding residues outside of that region. Starting on p. 6 of the specification, Applicants teach modifying the amino acid of SEQ ID NO: 2 (not residues 1-26 or 214-571) by replacing, deleting, inserting, and/or adding one or more amino acid residue. There is no written supported for the claimed polynucleotides. Such polynucleotides are considered to be new matter.

Conclusion

Claim 21 is allowed.

Claims 1, 4-6, and 19-20 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel K. Hunnicutt whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RKH
10/13/04


JANET ANDRES
PRIMARY EXAMINER